

In the Claims

Applicant has submitted a new complete claim set showing marked up claims with insertions indicated by underlining and deletions indicated by strikeouts and/or double bracketing.

Please amend pending claims 72-73, 84, and 104 as noted below.

Claims 1-71 (cancelled).

72 (currently amended). A method of transferring a gene into a recipient subject, comprising:

- (a) transfecting immortalized somatic cells *in vitro* with a DNA sequence by chemical or physical techniques to introduce the DNA sequence into the cells;
- (b) screening the resulting transfected immortalized somatic cells *in vitro* to select a cell, wherein the selected cell is stably transfected with the DNA sequence so that the selected cell has the permanent capacity to direct expression of the DNA sequence;
- (c) cloning and expanding the selected immortalized somatic cell *in vitro*; and
- (d) injecting the resulting transfected, screened, cloned, and expanded immortalized somatic cells into the recipient subject;

wherein the DNA sequence comprises the gene and a promoter capable of functioning in the immortalized somatic cells; and

wherein, following injection of the transfected, screened, cloned, and expanded immortalized somatic cells into the recipient subject, the DNA sequence is incapable of recombining with endogenous retroviral sequences, and the DNA sequence is incapable of initiating chronic viral infection in the recipient subject.

73 (currently amended). The method of claim 72, wherein the immortalized somatic cells are human cells.

74 (previously presented). The method of claim 73, wherein the human cells are selected from the group consisting of fibroblasts, myocytes, hepatocytes, kidney capsular cells, endothelial cells, epithelial cells of the gut, and pituitary cells.

75 (previously presented). The method of claim 73, wherein the gene encodes a hormone, an enzyme, or a receptor.

76 (previously presented). The method of claim 73, wherein the gene encodes human growth hormone.

77 (previously presented). The method of claim 73, wherein the gene encodes human insulin.

78 (previously presented). The method of claim 73, wherein the transfection comprises calcium phosphate-mediated transfection, microinjection, electroporation, or DEAE-dextran transfection.

79-81 (cancelled).

82 (previously presented). The method of claim 73, wherein the promoter is a regulatable promoter.

83 (previously presented). The method of claim 73, wherein the DNA sequence further comprises a selectable gene, and wherein the promoter is operably linked to the selectable gene.

84 (currently amended). The method of claim 73, wherein the screening step further comprises screening the resulting transfected immortalized somatic cells *in vitro* to select a cell possessing desired expression properties.

85-103 (cancelled).

104 (currently amended). A method of transferring a gene into a recipient subject, comprising:

- (a) providing immortalized somatic cells;
- (b) transfecting the immortalized somatic cells *in vitro* with a DNA sequence comprising the gene and a promoter capable of functioning in the immortalized somatic cells, wherein the gene encodes a gene product, and wherein the immortalized somatic cells are stably transfected with the gene so that the immortalized somatic cells have the permanent capacity to direct expression of the gene upon induction of the promoter;
- (c) screening the resulting transfected immortalized somatic cells *in vitro* to select a transfected immortalized somatic cell, wherein the screening comprises characterizing the transfected immortalized somatic cell with respect to expression and regulation of the gene by assaying for translation of the mRNA into the gene product;
- (d) cloning and expanding, *in vitro*, the transfected and screened immortalized somatic cell selected in step (c) to form 10^5 - 10^{10} transfected, screened, cloned, and expanded immortalized somatic cells, and
- (e) combining the 10^5 - 10^{10} transfected, screened, cloned, and expanded immortalized somatic cells with a physiologically acceptable buffer or carrier; and
- (f) injecting the resulting transfected, screened, cloned and expanded cell preparation into the recipient subject,

wherein, following injection of the transfected, screened, cloned, and expanded immortalized somatic cells into the recipient subject, the DNA sequence is incapable of recombining with endogenous retroviral sequences, and the DNA sequence is incapable of initiating chronic viral infection in the recipient subject.

105 (previously presented). The method of transferring a gene into a recipient subject of any one of claims 73 or 104, wherein the transfected gene encodes human growth hormone.

106 (previously presented). The method of transferring a gene into a recipient subject of any one of claims 73 or 104, wherein the transfected gene encodes insulin.

107 (previously presented). The method of transferring a gene into a recipient subject of any one of claims 73 or 104, wherein the DNA sequence integrates into the chromosome of the selected cell.

108 (previously presented). The method of transferring a gene into a recipient subject of any one of claims 73 or 104, wherein the DNA sequence replicates as an extrachromosomal plasmid.